

## REMARKS

The Office Action mailed on May 13, 2009 has been reviewed and the comments of the Examiner carefully considered. Claims 1-20 are pending and under consideration.

### **Rejections under 35 U.S.C. § 102**

Claims 1, 4-5, 13-15, and 18-19 currently stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Webster (US 4,541,426). Applicants respectfully disagree and assert that the claims are not anticipated for the following reasons.

It is well-settled that “[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” See *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990) and also MPEP § 2131 (quoting *Verdegaal Bros. v. Union Oil C. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). “The identical invention must be shown in as complete detail as is contained in the ...claim” *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Therefore, Nixon must describe each and every element of claims 1, 2 and 8-10 in order to anticipate these claims under section 102(b). However, Webster does not meet this burden. Webster does not teach or describe all of the claim limitations.

As a preliminary matter, Applicants note that Webster fails to teach several elements of claim 1, including:

“...a first portion which comprises a flexible plasticized hydrophilic polymer matrix having an internal cellular structure, and a second portion which comprises a flexible plasticized hydrophilic polymer matrix having a relatively continuous internal structure, wherein the first and the second portion are of the same material...” (emphasis added).

Accordingly, Webster does not anticipate the pending claims because: A) Webster teaches different materials, and B) Webster teaches different internal structures. Furthermore, Webster does not render the claims obvious, as it would render Webster unsatisfactory for its intended purpose if Webster were to be applied against the pending claims in an obviousness rejection.

A. Cited Art Teaches Different Materials

The layers of Webster are not of the same material as required by the presently-claimed invention. Contrary to the claimed invention, Webster requires that one layer is formed from a water swellable polymeric material and the other is formed from a non-swellable polymeric material, or a material which swells less than the first layer. This difference in layer materials is critical to the device of Webster, as illustrated in the following passage from Webster:

“When the first layer of the wound dressing of the present invention is placed in contact with a wet surface, moisture is taken up into the layer and the layer swells and so expands. The second layer being non-swellable or less swellable does not expand as much as the first layer. It has been found that when the two layers are adhered over their surfaces the stress caused by differential swelling is relieved by the second layer deforming and by the apertures opening. When the apertures are opened exudate can more readily pass through the dressing. As the exudation diminishes the first layer becomes drier and tends to return to its unswollen state. The apertures thereby tend to close. The presence of the dressing will keep the surface of the wound moist which is believed to be beneficial to rapid wound healing” (col. 3, lines 28-44).

The Webster reference teaches two distinct layers, and furthermore, two distinct layers having two distinct properties. Accordingly, Webster fails to disclose or teach each and every element of the presently-claimed invention.

Re-submitted herewith in support of Applicants’ present response to the Office Action is the Declaration of Patrick Trotter Pursuant to 37 C.F.R. § 1.132 (the “Declaration”). As set forth in the Declaration, the fact that the two layers as described by Webster have different properties is substantial evidence that the two layers are different, and have a different physical and/or chemical makeup (e.g., see Declaration, paragraphs 11 and 12).

Contrary to what is alleged in the Office Action, a second layer of material cannot be “made of the same material, just a different absorbancy.” This is because, in terms of materials science, the fact that the properties of the second layer are different than those of the first layer

can only be interpreted as meaning that the materials that make up the first and second layers are different.

Also as set forth in the Declaration, water absorbancy of a material is related to the ability of the material to absorb and retain water (e.g., see Declaration, paragraphs 9 and 10). The extent to which a material is absorbent is directly related to the hydrophilic versus the hydrophobic nature of the material. Materials hydrophobic in nature absorb very little water. The second layer described by Webster is a material that will have a water content of less than 5% when hydrated, preferably less than 3%, and most preferably, less than 1%. In other words, the second layer described by Webster is a material that is hydrophobic in nature. This is distinctly different from the hydrophilic, highly absorbent nature of the first layer described by Webster, which illustrates that the first and second layers described by Webster are different in nature, and therefore, are comprised of different materials.

Regarding the statement in the Office Action that Webster discloses that both layers may be polyamide or polyurethane, Applicants also refer to the enclosed Declaration (e.g., see Declaration, paragraphs 13 and 14). The terms “polyamide” and “polyurethane” are by themselves not sufficiently descriptive to allow the skilled artisan to determine whether any two polyamides or any two polyurethanes are identical or even similar. For example, not all polyurethanes are the same. As set forth in the Declaration, polyurethanes can be hydrophilic, hydrophobic, soft, hard, or even brittle in nature. The term “polyurethane” merely refers to a basic structure within a molecule, but does not fully or adequately describe the entire molecule. In other words, the term “polyurethane” may refer to many, many different types of materials. Similarly, the term “hydrogel” may refer to many different types of materials that fall within the broader genus of hydrogels.

Furthermore, while Webster explicitly describes the first layer as optionally being a hydrophilic polyurethane, Webster exemplifies the second layer as an Estane™, Kraton™, Hytrel™, etc..., all of which are hydrophobic materials, as well-known in the art. Webster further exemplifies second-layer materials as being polyethylene, polyisobutadiene, and neoprene, all of which are also hydrophobic materials. These materials would therefore have a low ability to bind or absorb water.

Applicants respectfully submit that the skilled artisan will understand the terms “same materials” and “different materials” to be consistent with Applicants’ use herein, and throughout the specification, including the claims. The usage of the term in the Webster patent is also consistent in this regard.

For example, the Office Action suggests that any polyurethane is the same as any other polyurethane. Essentially, the Office Action equates all polyurethanes as being “the same materials.” This is antithetical to the usage of the term “material” in materials science. As evidenced in the Webster patent, in fact, not all polyurethanes are equivalent, and therefore, not all polyurethanes can be classified as the “same material”. In the Webster patent, at lines 7-15 of column 3, there are described polyurethanes formed from polyethylene glycol, polypropylene glycol, and di-isocyanate and an ethanediol or ethylene diamine chain extender. The Office Action cannot possibly mean to imply that there is no difference between a polyurethane made from polyethylene glycol and a polyurethane made from di-isocyanate. Again, the implication that any and all different polyurethanes are “the same material” is antithetical to materials science, and is therefore incorrect. Furthermore, such an implication does not represent the understanding of the skilled artisan, as evidenced by Dr. Trotter’s declaration submitted herewith.

Additional evidence that all polyurethanes cannot be considered to be the “same material” can be found in the Webster patent in column 8, at lines 33-35. In particular, the Webster patent sets forth that the disclosed device may further comprise a third layer of material. Here, the patent makes specific note that the first and third layers of the device may be formed from “the same material”. By noting that the polyurethanes of the first and third layer can be the “same material”, the Webster patent necessarily points out that the polyurethanes of the first and second layers are different materials.

Referring now to Applicants’ specification, similar reference is made to the illustration that a hydrogel is a general term, and that different hydrogels may be considered to be different materials. Lines 8-10 on page 10 of the instant specification note that, where porous and continuous portions of the hydrogel composition [of the invention] are present, they may suitably comprise layers, which may be of the same or different materials. Applicants’ presently-pending claims are directed to those embodiments in which the claimed materials are the same.

Accordingly, because the layers disclosed in Webster are different, the rejection under 35 U.S.C. § 102(b) does not apply and Applicants respectfully submit that the rejection should be withdrawn.

B. Cited Art Teaches Different Internal Structures

The wound contacting hydrogel layer (*i.e.*, the “second portion”) in Applicants’ presently-pending claims has a “relatively continuous internal structure”, while the hydrogel layer distal to the wound (*i.e.*, the “first portion”) has an internal cellular structure.

Contrary to Applicants’ presently-claimed invention, the wound contacting layer in Webster does not have a relatively continuous internal structure, but rather is formed from a water swellable polymeric material having an internal cellular structure (*see, e.g.*, col. 2, lines 14-15; col. 2, lines 49-64; col. 5, lines 10-12; col. 9, lines 1-22; FIGS. 1-3).

As set forth in the Declaration, the term “cellular” refers to a structure having a similar appearance to biological cells, *i.e.*, small individual compartments (*e.g.*, *see* Declaration, paragraphs 15 and 16). This is the second structure that is described and taught in the Webster reference. In contrast, Applicants’ presently-pending claims are directed to a material with a second portion having a relatively continuous internal structure. The Declaration presents a detailed comparison and contrast between the continuous structure of Applicants’ pending claims, and the cellular structure disclosed by Webster. Furthermore, Applicants provide adequate description of a relatively continuous structure throughout the specification, and for example, in the first paragraph in the Brief Description of the Invention.

In the Office Action, it is hypothesized that the structure of Webster “may also be made of a natural polymer”. Applicants respectfully note again that the law of anticipation requires that the prior art must teach “each and every element” of the pending claims in order to anticipate the claims. A non-disclosed option or a possibility do not constitute a teaching for the purposes of 35 U.S.C. § 102.

Therefore, because Webster does not disclose or suggest a wound dressing comprising hydrogel layers of the same material, wherein the second layer is a relatively continuous structure, the cited reference does not disclose all of the elements of the Applicants’ claim 1, and the rejection of claim 1 under 35 U.S.C. § 102(b) should be withdrawn. Further, Applicants

submit that claims 4-5, 13-15, and 18-19 are thereby allowable as depending from an allowable independent claim.

C. Webster Cannot be Considered to Render the Claims Obvious

Furthermore, because Webster does not teach or suggest all of the limitations of claim 1, nor of dependent claims 4-5, 13-15, and 18-19, and because Webster requires different materials and limitations in order to operate as intended by the inventors of the Webster patent, Applicants' present claims cannot even be considered to be obvious in view of Webster. That is, the Webster reference cannot be properly modified to suggest the limitations of Applicants' pending claims, because, as set forth in MPEP 2143.01(V), a proposed modification of a prior art invention cannot render that invention "unsatisfactory for its intended purpose". If it does, "there is no suggestion or motivation to make the proposed modification". MPEP 2143.01(V). Replacing the material of either layer of the device taught by Webster so that both layers are of the same material would disallow the differential swelling that occurs (and is required) in Webster, thereby rendering that prior art invention unsuitable for its intended purpose.

**Rejections under 35 U.S.C. § 103**

1. Claims 2 and 20 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Webster. Applicants respectfully disagree and assert that the claims are not obvious for at least the reasons discussed above with respect to the anticipation rejection of claim 1. In particular, as Webster does not disclose or suggest a wound dressing comprising hydrogel layers of the same material, wherein the second layer is a relatively continuous structure, the cited reference does not disclose all of the elements of claims 2 and 20. The Office has not provided any teaching which cures this deficiency. Therefore, Applicants respectfully request that the rejection of claims 2 and 20 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.
2. Claim 3 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Webster in view of Takahashi et al. (US 5,972,452). Applicants respectfully disagree and assert that the claims are not obvious for at least the reasons discussed above with respect to the anticipation rejection of claim 1. In particular, as Webster does not disclose or suggest a wound

3. dressing comprising hydrogel layers of the same material, wherein the second layer is a relatively continuous structure, the cited reference does not disclose all of the elements of claim 3.

Takahashi et al. does not disclose a wound dressing comprising a wound contacting hydrogel layer having a relatively continuous internal structure, or a hydrogel layer distal to the wound having an internal cellular structure, wherein these layers are of the same material. Thus, as Takahashi et al. cannot cure the deficiencies of Webster, claim 3 is thereby allowable as written as depending from an allowable independent claim. Applicants respectfully request that the rejection of claim 3 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

3. Claims 6-12 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Webster in view of Nielsen (US Published Appln. No. 2003/0153860). Applicants respectfully disagree and assert that the claims are not obvious for at least the reasons discussed above with respect to the anticipation rejection of claim 1. In particular, as Webster does not disclose or suggest a wound dressing comprising hydrogel layers of the same material, wherein the second layer is a relatively continuous structure, the cited reference does not disclose all of the elements of claim 1, much less claims 6-12.

Nielsen does not disclose a wound dressing comprising a wound contacting hydrogel layer having a relatively continuous internal structure, or a hydrogel layer distal to the wound having an internal cellular structure, wherein these layers are of the same material. Thus, as Nielsen cannot cure the deficiencies of Webster, claims 6-12 are thereby allowable as written as depending from an allowable independent claim. Applicants respectfully request that the rejection of claims 6-12 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

4. Claims 16-17 currently stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Webster in view of Gilman et al. Applicants respectfully traverse this basis for rejection and request reconsideration and withdrawal thereof. Applicants respectfully disagree and assert that the claims are not obvious for at least the reasons discussed above with respect to the anticipation rejection of claim 1. In particular, as Webster does not disclose or suggest a wound dressing comprising hydrogel layers of the same material, wherein the second

layer is a relatively continuous structure, the cited reference does not disclose all of the elements of claims 16-17.

Gilman et al. discloses an adhesive wafer, which is especially suitable for use as a faceplate for an ostomy appliance but may also be used as a wound dressing, has an adhesive layer of hydrocolloid-containing skin barrier material and a flexible backing layer extending over one surface of the adhesive layer. Gilman et al. does not disclose a wound dressing comprising a wound contacting hydrogel layer having a relatively continuous internal structure, or a hydrogel layer distal to the wound having an internal cellular structure, wherein these layers are of the same material. Thus, as Gilman et al. cannot cure the deficiencies of Webster, claims 16-17 are thereby allowable as written as depending from an allowable independent claim. Applicants respectfully request that the rejection of claims 16-17 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.



**Conclusion**

Applicants respectfully submit that the pending claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5809 to clarify any unresolved issues raised by this response.


The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5026) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

**HUGH S. MUNRO, ET AL.**

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By:

  
**Thomas M. Sossong, Jr., Ph.D.**  
Registration No. **48,463**  
**MORGAN, LEWIS & BOCKIUS LLP**  
1701 Market Street  
Philadelphia, PA 19103-2921  
Telephone: (215) 963-5809  
Facsimile: (215) 963-5001  
E-Mail: [tsossong@morganlewis.com](mailto:tsossong@morganlewis.com)